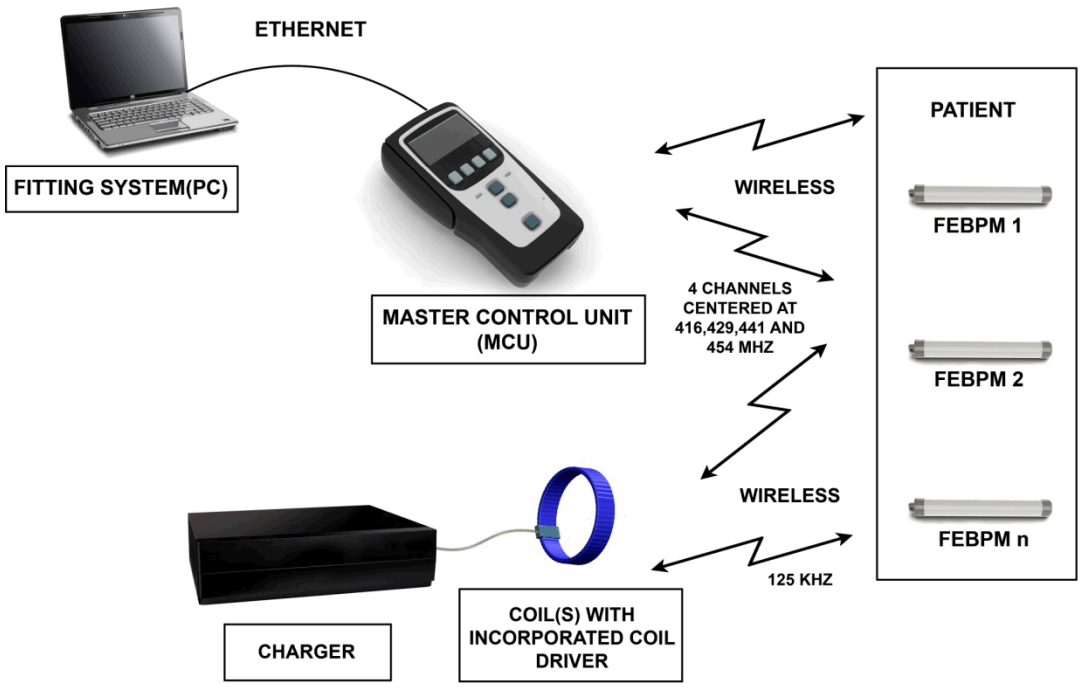
Medical Micropower Network Service in the 413-457 MHz Band

June, 2011

Alfred Mann Foundation

- Founded in 1985
- Non-profit engaged solely in medical research
- Initiated R&D on numerous advanced medical devices
  - Cochlear implant (profound hearing loss)
  - Retinal prosthesis (vision loss)
  - Fully implantable glucose sensor (diabetes)
  - Fully implantable drug pump (pain, diabetes)
  - Microstimulator System (paralysis)

AMF Microstimulator System



IP
- 68 issued patents and several pending

Economics
- Needle injection in Dr. office under local reduces costs

Wireless
- RF communications 100 times per second

Objective

Secure secondary allocation of spectrum for transformative medical technology

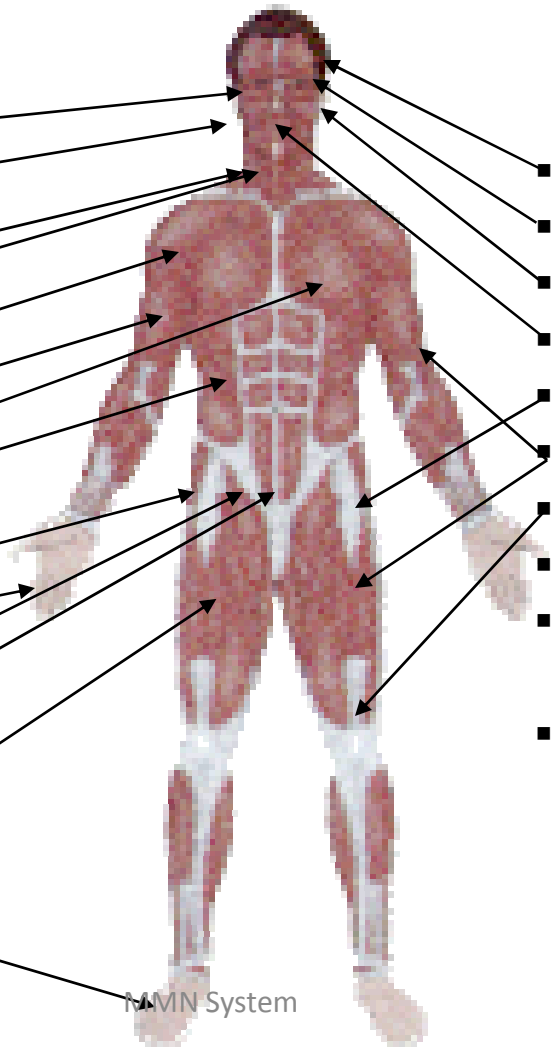
413 – 419 MHz	426 – 432 MHz	438 – 444 MHz	451 – 457 MHz
Emergency Land Mobile Radio	Radar	Radar	Commercial Channel/Land Mobile Radio

AMF Microstimulator System

- Movement Disorders
  - Restores function and sensation to paralyzed limbs and organs
    - Traumatic brain injury (signature injury from conflicts)
    - Stroke (~800,000 per year in US)
    - Spinal cord injury (~12-15K per year in US)
    - Multiple Sclerosis
    - Cerebral palsy
  - 2% of all Americans live with paralysis

- Advanced Prosthesis
  - Provides wireless sensation and control to next generation prosthesis
    - Supported by NIH and part of DARPA arm project
    - Replaces less effective surface myoelectric sensors
    - Direct neural control

Revolutionizing Medicine



- Eyelid droop
- Facial palsy
- Shoulder Subluxation
- Sleep apnea
- Muscle atrophy
- Arm/hand rehab
- Cardiac assist
- Cough
- Pressure Ulcers
- Spasticity
- Bladder control
- Bowel control
- Gait rehabilitation
- Foot drop

- Parkinson's disease
- Cerebral Palsy
- Vertigo
- Dysphagia
- FES Exercise
- Smart Prosthesis
- Arthritis
- Nerve Repair
- Nerve Regrowth

- And many more to come

Project Evolution

- 11 years in development
- 120 person team consisting of approximately 90 scientists of various disciplines
- To date, ~$115 million (in tax exempt dollars) invested in development
  - Estimate $120 million to complete first clinically viable system
- Working with FDA, FCC, NTIA and other regulators for several years

Experimental Evolution

2005	• FCC grants experimental license for 410-470 MHz • Renewed in 2009
2005 - 2007	• UK stroke clinical study • Restored movement to paralyzed hands and arms of stroke patients
2006 - 2008	• *In vivo* studies demonstrate biocompatibility • *In vitro* studies verify communications operations
2008	• 2 implants in laboratory animals • Stimulation, communication and battery recharge confirmed
2009	• Walter Reed Army Medical Center Study • Movement restored to lower limbs of spinal cord injured patient
2010	• Version 1 completed in Q1, 2010; Version 2 engineering completed in Q4, 2010 • Human clinical trials planning in 2011

No Comparable System Exists Anywhere in the World

FCC Proceeding

Chronology of Proceedings

Sept 2007	• AMF files Petition for Rulemaking
March 2009	• FCC issues NPRM
Q2, Q3 2009	• Public comment period
January 2010	• Interference testing commences
January 2011	• Interference testing completed

Interference Testing

2005 2010	• Ongoing dialog with DOD and government
Q1 2008	• NTIA, NII identify JSC for system testing • AMF initiates discussions with JSC
2008 2010	• JSC contracting process
Q1 2010	• JSC testing commences
Q2 2010	• AMF engages Aerospace corporation to conduct testing • Designed to fill in gaps in JSC testing
Since Q3, 2010	• Interference testing completed • AMF supplied additional data to supplement test findings
March 2011	• JSC publishes ITT Memorandum reconciling JSC and Aerospace testing

Testing Summary

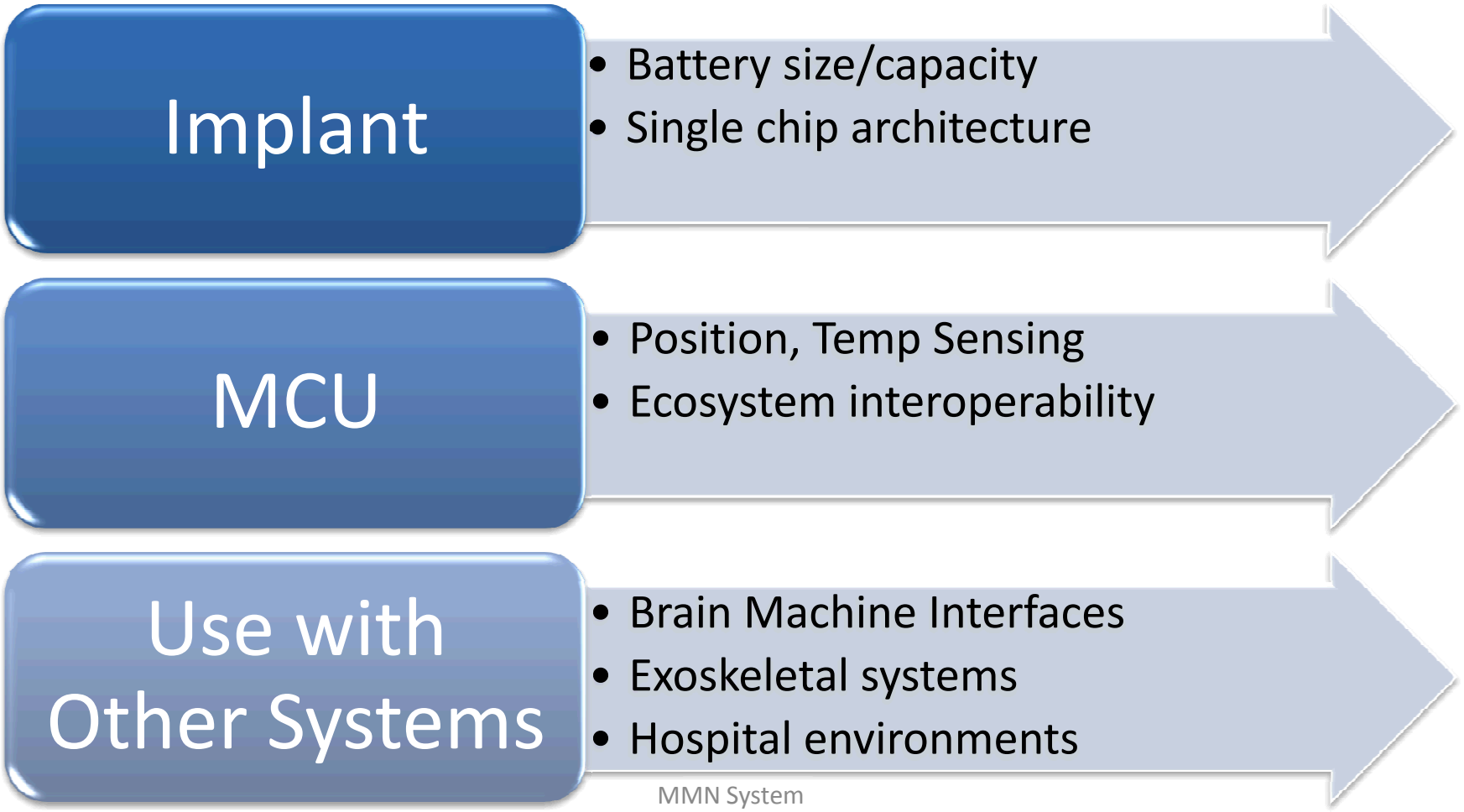
- JSC Report
  - No harmful interference from MMN to incumbent systems
  - MMN system's interference mitigation measures may effectively eliminate harmful effects of interfering signals from LMRs and radar incumbents
  - Further testing requested to confirm viability of mitigation measures
- Aerospace Report
  - Examined mitigation measures
  - Concluded that MMN system can
    - Spectrally excise narrow band incumbent signals
    - Change channels without suspending critical functions
    - Shutdown gracefully in the face of overwhelming interference
- Reconciliation Memo (JSC and ITT)
  - ITT, on behalf of JSC, concluded that Aerospace confirmed that the MMN system can successfully mitigate harmful interference and thus put to rest the remaining questions raised in the JSC report

Where We Go From Here

AMF Sponsored Clinical Applications

Collaborator	Medical Condition	Timing
USC	Dysphagia (head and neck cancer patients)	FDA Approval Pending
Veteran's Administration	TBI upper extremity rehabilitation	FDA Approval Pending
Shriner's Children's Hospital	Spasticity relief for pediatric cerebral palsy patients	Q2, 2012
Walter Reed/Bethesda Naval	Prevention of Decubitus Ulcers	Planning phases

Future Technical Development



Appendix

Current Channel Allocation

INTERNATIONAL TABLE	UNITED STATES TABLE		FCC RULE PART(S)
* * * * *	**Federal Table (MHz)**	**Non-Federal Table (MHz)**	
* * * * *	**410-420** FIXED US13 MOBILE SPACE RESEARCH (space-to-space) 5.268 G5 US399	**410-420** US13 US399	**Private Land Mobile (90)** **Personal (95)**
* * * * *	**420-450** RADIOLOCATION US217 G2 G129 5.286 US7 US87 US230 US397 G8 US399	**420-450** Amateur US7 NG135 5.282 5.286 US87 US217 US230 US397 US399	**Private Land Mobile (90)** **Amateur (97)** **Personal (95)**
* * * * *	**450-454** 5.286 US87 US399	**450-454** LAND MOBILE 5.286 US87 US399 NG112 NG124	**Auxiliary Broadcasting (74)** **Private Land Mobile (90)** **Personal (95)**
* * * * *	**454-456**	**454-455** FIXED LAND MOBILE US399 NG12 NG112 NG148	**Public Mobile (22)** **Maritime (80)** **Personal (95)**
		455-456 LAND MOBILE US399	**Auxiliary Broadcasting (74)** **Personal (95)**
* * * * *	**456-460** 5.287 5.288 US399	**456-460** FIXED LAND MOBILE 5.287 5.288 US399 NG112 NG124 NG148	**Public Mobile (22)** **Maritime (80)** **Private Land Mobile (90)** **Personal (95)**